

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (currently amended) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as active ingredients, said method comprising:
 - (a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes and shapes;
 - (b) mixing said active ingredients and at least one chosen excipient so as to obtain a powdered mixture;
 - (c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;
 - (d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules; and
 - (e) forming said granules into unitary dosage forms,

wherein the method does not comprise addition of a loss-compensatory overage amount of Pyridoxine HCl.
2. (currently amended) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as active ingredients, said method comprising:
 - (a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes and shapes;
 - (b) mixing said active ingredients and at least one chosen excipient so as to obtain a powdered mixture;

- (c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;
- (d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules;
- (e) mixing said granules with at least one chosen excipient so as to obtain a granular mixture; and
- (f) forming said granular mixture into unitary dosage forms,

wherein the method does not comprise addition of a loss-compensatory overage amount of Pyridoxine HCl.

3-5. (cancelled)

6. (previously presented) The method of claim 1 wherein the step of forming said granular mixture into unitary dosage forms comprises compressing said granular mixture into a tablet shape.

7. (previously presented) The method of claim 6 wherein the tablet shape is provided with a coating.

8. (previously presented) The method of claim 7 wherein said coating is an enteric coating.

9. (previously presented) The method of claim 1 wherein the step of forming said granular mixture into unitary dosage forms comprises loading said granular mixture into an open capsule and thereafter closing said capsule.

10. (cancelled)

11. (currently amended) The method of claim 1 wherein the active ingredients in the unitary dosage forms comprise equal parts of Pyridoxine HCl and Doxylamine Succinate.
12. (currently amended) The method of claim 1 wherein the active ingredients in the unitary dosage forms consist of equal parts of Pyridoxine HCl and Doxylamine Succinate.
13. (new) The method of claim 1, wherein the chosen mesh size is 16.
14. (new) The method of claim 1, wherein the unitary dosage forms do not contain a loss-compensatory overage amount of Pyridoxine HCl.
15. (new) The method of claim 2 wherein the step of forming said granular mixture into unitary dosage forms comprises compressing said granular mixture into a tablet shape.
16. (new) The method of claim 15 wherein the tablet shape is provided with a coating.
17. (new) The method of claim 16 wherein said coating is an enteric coating.
18. (new) The method of claim 2 wherein the step of forming said granular mixture into unitary dosage forms comprises loading said granular mixture into an open capsule and thereafter closing said capsule.
19. (new) The method of claim 2 wherein the active ingredients in the unitary dosage forms comprise equal parts of Pyridoxine HCl and Doxylamine Succinate.

20. (new) The method of claim 2 wherein the active ingredients in the unitary dosage forms consist of equal parts of Pyridoxine HCl and Doxylamine Succinate.
21. (new) The method of claim 2, wherein the chosen mesh size is 16.
22. (new) The method of claim 2, wherein the unitary dosage forms do not contain a loss-compensatory overage amount of Pyridoxine HCl.
23. (new) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as active ingredients, said method comprising:
- (a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes and shapes;
 - (b) mixing said active ingredients and at least one chosen excipient so as to obtain a powdered mixture;
 - (c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;
 - (d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules; and
 - (e) forming said granules into unitary dosage forms,
- wherein the unitary dosage forms do not contain a loss-compensatory overage amount of Pyridoxine HCl.
24. (new) A method for the preparation of pharmaceutical dosage forms comprising Pyridoxine HCl and Doxylamine Succinate as active ingredients, said method comprising:

- (a) providing said Pyridoxine HCl and Doxylamine Succinate active ingredients in the form of powders having different granular sizes and shapes;
 - (b) mixing said active ingredients and at least one chosen excipient so as to obtain a powdered mixture;
 - (c) compacting said powdered mixture in a roller compactor apparatus to obtain a compacted product;
 - (d) breaking and sieving said compacted product to a chosen mesh size to obtain similar sized granules;
 - (e) mixing said granules with at least one chosen excipient so as to obtain a granular mixture; and
 - (f) forming said granular mixture into unitary dosage forms,
- wherein the unitary dosage forms do not contain a loss-compensatory overage amount of Pyridoxine HCl.

- 25. (new) The method of claim 1, wherein the similar sized granules present content uniformity in terms of active ingredients.
- 26. (new) The method of claim 2, wherein the similar sized granules present content uniformity in terms of active ingredients.
- 27. (new) The method of claim 23, wherein the similar sized granules present content uniformity in terms of active ingredients.
- 28. (new) The method of claim 24, wherein the similar sized granules present content uniformity in terms of active ingredients.